K123449

5. 510(K) SUMMARY

MAR 5 2013

BIOMONDE
LARVAL DEBRIDEMENT THERAPY PRODUCTS – LARVAE 100/200/300
(PER 21CFR 807.92)

1. SUBMITTER/510(K) HOLDER

BioMonde (*a trading name of ZooBiotic Limited*)
Units 2-4 Dunraven Business Park
Coychurch Road
Bridgend
CF31 3BG
United Kingdom

Contact Person: Suzanne Morgan
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Date Prepared: October 18, 2012

2. DEVICE NAME

Proprietary Name:	Larval Debridement Therapy Products – Larvae 100/200/300
Common/Usual Name:	Maggots
Classification Name:	Unclassified

3. PREDICATE DEVICE

Medical Maggots (K033391; Procode: NQK)

4. DEVICE DESCRIPTION

The BioMonde Larvae 100/200/300 products are live larvae, stage I and II, of the green bottle fly *Lucilia sericata*. They are manufactured in three (3) configurations:

- Larvae100: at least 100 larvae per container
- Larvae200: at least 200 larvae per container
- Larvae300: at least 300 larvae per container

The larvae are derived from disinfected fly eggs. Larvae are transferred under controlled manufacturing conditions into transport tubes which are additionally boxed for transport.

Upon arrival at the treatment location, they are applied to the wound and covered with permeable and absorbent dressings (not provided).

5. Indication for Use/Intended Use

The BioMonde Larval Debridement Therapy Products – Larvae 100/200/300 are indicated for debridement of non-healing necrotic skin and soft tissue wounds, including pressure ulcers, venous stasis ulcers, neuropathic foot ulcers, and non-healing traumatic or post-surgical wounds.

6. Summary of Technological Characteristics Compared to the Predicate Device/s

Characteristics shared by the BioMonde and the predicate device, the Monarch Labs Medical Maggots is based on intended use, indications for use, technological characteristics, performance characteristics, and operational characteristics.

7. Summary of Non-clinical Performance Testing as Basis for Substantial Equivalence

Testing that demonstrates that the product fulfills design and performance specifications. Side by side testing of the performance of the BioMonde product and the predicate demonstrates substantial equivalence in performance.

8. Summary of Clinical Testing as Basis for Substantial Equivalence

No clinical data were included in this 510(k) Premarket Notification.

9. Summary of other Information

Other information provided in the 510(k) included manufacturing information and information from the scientific literature.

10. Conclusions Drawn From Non-clinical and Clinical Tests

Based on the information provided in this 510(k) Premarket Notification, BioMonde has determined that the Larval Debridement Therapy Products – Larvae 100/200/300 are substantially equivalent to the predicate device, Medical Maggots, and that differences do not raise new safety and effectiveness questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center– WO66-G609
Silver Spring, MD 209930002

Biomonde (A Trading name of Zoobiotic Limited)
% Aptiv Solutions
Ms. Rosina Robinson RN, MED, RAC
Affiliate Principle Regulatory Consultant
225 Turnpike Road
Southborough, Massachusetts 01772

Letter dated: March 5, 2013

Re: K123449
Trade/Device Name: BioMonde Larval Debridement Therapy Products-Larvae 100/200/300
Regulation Class: Unclassified
Product Code: NQK
Dated: February 07, 2013
Received: February 14, 2013

Dear Ms. Robinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE

510(k) Number (if known):

Device Name: BioMonde Larval Debridement Therapy Products – Larvae 100/200/300

Indications for Use:

The BioMonde Larval Debridement Therapy Products – Larvae 100/200/300 are indicated for debridement of non-healing necrotic skin and soft tissue wounds, including pressure ulcers, venous stasis ulcers, neuropathic foot ulcers, and non-healing traumatic or post-surgical wounds.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K123449